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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,983	12/03/2004	Luppo Edens	BJS-4662-357	1387

23117 7590 05/10/2007
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EXAMINER	
LILLING, HERBERT J	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
05/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,983	EDENS ET AL.	
	Examiner	Art Unit	
	HERBERT J. LILLING	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 16-21* is/are pending in the application.

4a) Of the above claim(s) *7-15 and 22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 16-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *7-15 and 22-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *July 7, 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of the election response filed April 05, 2007.

2. Claims 1-24 remain pending in this instant application which application is a 371 of PCT/EP03/05876 filed June 03, 2003 and claims benefit to EPO 02100667.1 filed June 04, 2002.

3. Applicant has elected Invention I, claims 1-5 and 16-21.

Claims 6-15 and 22-24 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 5, 2007.

The restriction is proper as indicated in the previous office action that this application contains inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The arguments that there is no extreme burden on this Examiner to search and examine the various groups would required various different computerized strategies as well as different subclasses which would be extremely burdensome.

Applicant has indicated that there is no evidence that there is prior art which this Examiner will show in the following paragraphs that the subject matter are not so linked as to form a single general inventive concept. In the Sept 08, 2004 statement by the PCT Examiner indicated the following which art is evidence of the lack of a single general concept:

V.Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement:
Statement Novelty (N) Yes: Claims 1-15
No: Claims
Inventive step (IS) No: Claims:1-15
Yes: Claims
Industrial applicability (IA):Yes:Clms 1-15
No: Claims

The restriction as well as the election of species are proper according to PCT Rules and U. S. rules pertaining to PCT applications.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 16-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claimed inventions.

This Examiner will never allow a product per se that is claimed by functional language without sufficient number of properties that define the product per se. Based on the claimed language, the instant specification does not support the claimed product(s) in view of the fact the specification does not disclose or teach one single specific tripeptides.

The language of the claims must make it clear what subject matter the claims encompass to adequately delineate their "metes and bounds" before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover which in this case all products within the bounds of having at least one tripeptides having a terminal proline amino acid. Applicant has failed to provide a specification commensurate in scope with the claimed subject matter.

Claims 1-5 and 16-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for products as prepared by the examples, does not reasonably provide enablement for the products based on functional language that encompasses hundreds of possible products having proline as the terminal end of the containing a tripeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with these claims.

Applicant is required to include the structure of all of the tripeptides encompassed in the claimed subject matter which includes not only for claims that are drawn to 100 mol % but to compositions containing less than 100 mol% which composition contains unknown di, tetra to heptapeptides for this Examiner to search and examine the full scope of the claimed subject matter. In addition, the percentage of each fraction for the claimed composition as well as the additional ingredients in the composition per se.

Therefore, the specification has been found to be **TOTALLY DEFECTIVE** to support the claimed product(s) as defined by claims 1-5 and 16-21.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 and 16-21 are rejected under 35 U.S.C. 102(b/e) as anticipated by

1. Ito et al "A tripeptides 'anticodon' deciphers stop codons in messenger RNA", Nature 403 pg 680-684 (February 10, 2000);

2. Pfister, E.A., "Identification and Synthesis of Chemotactic Tripeptides From Alkali-Degraded Whole Cornea A Study of N-Acetyl-Proline-Glycine-Proline and N-Methyl-Proline-Glycine-Proline," Investigative Ophthalmology and Visual Science; Jun. 1995; 36(7): 1306-16 ;

3. Haddox et al., U.S. 6,310,041 ;

4. St. Pierre et al., U.S. 5,856,308.

Each of the references teaches a product having 100% mol of isolated tripeptides containing a terminal proline that is considered to be within the scope of all of the claimed products.

St. Pierre et al discloses the following:

In attempts to clarify the correlation between the primary and secondary structures of collagen, a variety of polypeptides with repeating sequences (Pro-Pro-Gly), (Pro-Hyp-Gly), and others have been synthesized and evaluated during the past twenty years.

Haddix et al teaches the following:

> Preferably, the neutrophil chemoattractant is selected from the group consisting of N-acetyl-PGP, N-acetyl-PGX, N-methyl-PGX, N-methyl-PGP and small peptide chemoattractants containing proline and glycine.
>
> Five complementary peptides were tested as potential inhibitors of **N-acetyl-PGP**: ------ RTR (SEQ ID NO:2), RTRGG (SEQ ID NO:3), RTR dimer, RTR tetramer, and ASA (SEQ ID NO:4) tetramer. In addition, the RTR tetramer and both monomeric peptides (RTR and RTRGG) were tested, separately, for inhibition of the ultrafiltered tripeptide chemoattractants or LTB.sub.4 ----- .;

which tripeptide is within the scope of the claims.

Pfister teaches the hydrolysates from cornea to yield the tripeptides N-Acetyl-Proline-Glycine-Proline and N-Methyl-Proline-Glycine-Proline.

St. Pierre et al discloses the following:

> The studies also demonstrated that collagen contains a large number of tripeptide sequences of the form of Pro-Hyp-Gly, Pro-X-Gly, or X-Hyp-Gly, where X is an amino acid residue other than Pro, Gly, or Hyp.

> Pioneering work on synthetic collagen models has also been done with polydisperse mixtures of sequential polytripeptides containing Pro and Gly (J. Mol. Biol. 43:461, 1969) . Monodisperse oligotripeptides of (Pro-Pro-Gly).sub.n or (Pro-Hyp-Gly).sub.n sequences, where n=2-10, have also been prepared, with X-ray diffraction patterns of the former, wherein n was 4 or greater showing collagen-like diffraction patterns. Circular dichroism spectra of penta- and octadecapeptide films cast from solution are consistent with the conformation of collagen (Biopolymers 17:1215, 1978).
>
> The studies also demonstrated that collagen contains a large number of tripeptide sequences of the form of Pro-Hyp-Gly, Pro-X-Gly, or X-Hyp-Gly, where X is an amino acid residue other than Pro, Gly, or Hyp.
> Pioneering work on synthetic collagen models has also been done with polydisperse mixtures of sequential polytripeptides containing Pro and Gly (J. Mol. Biol. 43:461, 1969) . Monodisperse oligotripeptides of (Pro-Pro-Gly).sub.n or (Pro-Hyp-Gly).sub.n sequences, where n=2-10, have also been prepared, with X-ray diffraction patterns of the former, wherein n was 4 or greater showing collagen-like diffraction patterns. Circular dichroism spectra of penta- and octadecapeptide films cast from solution are consistent with the conformation of collagen (Biopolymers 17:1215, 1978).

St. Pierre teaches a tripeptides within the scope of the claimed product(s) for the broad language as submitted:

> "1. A protein hydrolysate which is rich in tripeptides whereby the tripeptides are rich in proline at one end thereof.";

the tripeptides(s) is any product that can be isolated from the hydrolysis of any protein. The language of the claims do not exclude the reference tripeptides(s).

6. No claim is allowed.

7. Applicant has elected product claims. Applicant is required to be in full compliance with the following for rejoinder of the process claims upon the allowance of the elected product claims.

F.P.: Ochiai/Brouwer Rejoinder form paragraph:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**. or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit **1657**
May 07, 2007

Dr. Herbert J. Lilling
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